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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,720	06/23/2003	Make Morris	12873/04604	8692
24024	7590	06/21/2005	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

①

<b>Office Action Summary</b>	<b>Application No.</b> 10/601,720	<b>Applicant(s)</b> MORRIS ET AL.	
	<b>Examiner</b> Teena Mitchell	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The indicated allowability of claims 16-20 is withdrawn after further review of the specification.

#### ***Claim Rejections - 35 USC § 112***

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

**Claims 16-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claims 16-20, while the limitations of the claimed set of instructions appears in the claims, there is no support for the claimed set of instructions in the specification. With respect to claims 21 and 26, the specification does not provide support for "inhalation state threshold value" it appears that the system functions as noted on page 8 [0024] of the specification where "...the difference between the instantaneous and average valve position is integrated over time and stored in memory. The summation of six such integrations is used to determine the start of inhalation breathing state, if the summation is greater than the threshold, the start of inhalation breathing state has occurred...". Then in claims 22 and 27, ..." predefined function..." it is unclear what the predefined function is as the specification does not define such function. With respect**

to claim 26, "...memory defining a plurality of method steps..." the specification does not provide support for such memory having the claimed method steps.

***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 21-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gruenke et.al. (5,549,106).**

Gruenke in a breathing gas delivery device discloses a pressure sensor (40, 700), a blower (18), a valve (16), and a controller (20) connected to the sensor, blower and valve; sensing a pressure associated with the delivery of the breathing gas (Abstract; Fig. 6; Col. 3, lines 9-35; inhalation/exhalation); changing the valve position in response to a change in the sensed pressure (Figs. 6, 13); detecting a start of inhalation by determining if the valve position has increased beyond a start of inhalation state threshold value (Col. 3, lines 3-50); detecting an end of inhalation state by determining if the valve position has fallen below an end of inhalation state threshold value (Fig. 6; Col. 6; lines 23-67 and Col. 7, lines 1-33); delivering the breathing gas at least at a first positive pressure above ambient pressure after detection of the start of inhalation state (Fig. 6; Col. 6, lines 23-67 and Col. 7, lines 1-33); and delivering the breathing gas at a

second pressure after detection of the end of inhalation state wherein the second pressure is less than the first pressure (Fig. 6; Col. 6, lines 23-67 and Col. 7, lines 1-33).

With respect to claim 22, Gruenke discloses the step of delivering the breathing gas from the second pressure to the first pressure according to a predefined function and prior to the detection of the next start of inhalation state (Figs. 31A-B; step 3112).

With respect to claim 23, Gruenke discloses wherein the predefined function is a linear function (step 3112, techniques well known to those skilled in the art (Col. 26, lines 23-25).

With respect to claim 24, Gruenke discloses the predefined function is associated with a sensed pressure associated with a patient interface (14).

With respect to claim 25, Gruenke discloses wherein the second pressure comprises at least an ambient pressure (Col. 2, lines 52-67).

With respect to claim 26, note rejection of claim 21 above and Gruenke discloses a memory (Fig. 8, Col. 8, lines 26-34).

With respect to claim 27, note rejection of claim 22 above.

With respect to claim 28, note rejection of claim 23 above.

With respect to claim 29, note rejection of claim 24 above.

With respect to claim 30, note rejection of claim 25 above.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show gas delivery devices:

Art Unit: 3743

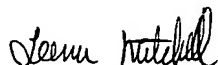
2005/0034724; 6,895,964; 2004/0035422; 2004/0103896; 6,745,770; 6,443,154;

2001/0035187; 6,357,463.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell  
Examiner  
Art Unit 3743  
June 17, 2005